

REMARKS

Claims 1-6, 8, 10, 15-23 and 25-35 are pending in the application.

In view of the remarks below, applicants respectfully request reconsideration and withdrawal of the rejection set forth in the August 8, 2006 Office Action.

Provisional Rejection Under Obviousness-Type Double Patenting

Claims 1-6, 8, 10, 15-23 and 25-28, and 30-35 are provisionally rejected under obviousness-type double patenting over claims 1-34 of copending Application No. 10/348,381 and over claims 1-34 of copending Application No. 10/348,399.

Applicants do not agree with the Examiner's position on these provisional double patenting rejections. However, Applicants will address these rejections once the claims in the subject application are found otherwise allowable.

Rejection under 35 USC § 112, First Paragraph

The Examiner rejected claims 1-6, 8, 10, 15-23, and 25-35 under 35 USC § 112, first paragraph, as allegedly not enabled for muscaric agonists and amyloid aggregation inhibitors.

In response, applicants are submitting herewith supplementary abstracts of references which were available prior to the filing date of the subject application, and therefore provide enabling support for the following additional compounds recited in the claims: muscaric agonist and amyloid aggregation inhibitors. The references supporting each specific additional recited compound are listed herein below for the convenience of the Examiner:

Muscarinic Agonists

1. Hollander E. Davidson M. Mohs RC. Horvath TB. Davis BM. Zemishlany Z. Davis KL. RS 86 in the treatment of Alzheimer's disease: cognitive and biological effects. Biological Psychiatry. 22(9):1067-78, 1987 Sep.
2. Fisher A. Heldman E. Gurwitz D. Haring R. Karton Y. Meshulam H. Pittel Z. Marciano D. Brandeis R. Sadot E. Barg Y. Pinkas-Kramarski R. Vogel Z. Ginzburg I. Treves TA. Verchovsky R. Klimowsky S. Korczyn AD. M1 agonists for the treatment of Alzheimer's disease. Novel properties and clinical update. Annals of the New York Academy of Sciences. 777:189-96, 1996 Jan 17.
3. Nakahara N. Iga Y. Saito Y. Mizobe F. Kawanishi G. Beneficial effects of FKS-508 (AF102B), a selective M1 agonist, on the impaired working memory in AF64A-treated rats. Japanese Journal of Pharmacology. 51(4):539-47, 1989 Dec.
4. Bromidge SM. Brown F. Cassidy F. Clark MS. Dabbs S. Hadley MS. Hawkins J. Loudon JM. Naylor CB. Orlek BS. Riley GJ. Design of [R-(Z)]-(+)-alpha-(methoxyimino)-1-azabicyclo[2.2.2]octane-3-acetonitrile (SB 202026), a functionally selective azabicyclic muscarinic M1 agonist incorporating the N-methoxy imidoyl nitrile group as a novel ester bioisostere. Journal of Medicinal Chemistry. 40(26):4265-80, 1997 Dec 19.

5. Bodick NC, Offen WW, Shannon HE, Satterwhite J, Lucas R, van Lier R, Paul SM. The selective muscarinic agonist xanomeline improves both the cognitive deficits and behavioral symptoms of Alzheimer disease. *Alzheimer Disease & Associated Disorders*. 11 Suppl 4:S16-22, 1997.
6. Plate R, Plaum MJ, de Boer T, Andrews JS, Rae DR, Gibson S. Synthesis and muscarinic activities of 3-(pyrazolyl)-1,2,5,6-tetrahydropyridine derivatives. *Bioorganic & Medicinal Chemistry*. 4(2):227-37, 1996 Feb.
7. Fisher A, Heldman E, Gurwitz D, Haring R, Karton Y, Meshulam H, Pittel Z, Marciano D, Brandeis R, Sadot E, Barg Y, Pinkas-Kramarski R, Vogel Z, Ginzburg I, Treves TA, Verchovsky R, Klimowsky S, Korczyn AD. M1 agonists for the treatment of Alzheimer's disease. Novel properties and clinical update. *Annals of the New York Academy of Sciences*. 777:189-96, 1996 Jan 17.

Amyloid Aggregation Inhibitors

1. Emmerling MR, Spiegel K, Watson MD. Inhibiting the formation of classical C3-convertase on the Alzheimer's beta-amyloid peptide. *Immunopharmacology*. 38(1-2):101-9, 1997 Dec.
2. Carr DB, Goate A, Phil D, Morris JC. Current concepts in the pathogenesis of Alzheimer's disease. *American Journal of Medicine*. 103(3A):3S-10S, 1997 Sep 22.
3. Parnetti L, Senin U, Mecocci P. Cognitive enhancement therapy for Alzheimer's disease. The way forward. *Drugs*. 53(5):752-68, 1997 May.

Applicants submit that, in view of the cited references, the individual of ordinary skill in the art would readily be able to identify specific members of any of the aforementioned classes and formulate them with the active ingredient of instant formula I using principles and procedures that are common knowledge in the art, the guidance provided by the instant specification and readily available publications. For the foregoing reasons, applicants respectfully submit that the specification is enabling to those skilled in the art seeking to formulate the compounds of formula I into the pharmaceutical compositions that include the classes of active ingredients recited in claim 1.

In view of the remarks above, applicants respectfully submit that claims 1-6, 8, 10 and 15-23 and 25-35 are patentable under 35 USC § 112, first paragraph, and therefore request that the Examiner withdraw the rejection.

Rejection under 35 USC § 112, Second Paragraph

The Examiner rejected claim 25 and 26 under 35 USC § 112, second paragraph, because the terms "neurotrophic factor is NFG" and "the agent that slows or arrests Alzheimer's disease is a cognition enhancer" allegedly lack antecedent basis.

In response, Applicants respectfully note that antecedent basis is found, for example, on page 1 of the speciation, paragraph 2, lines 23-31.

"The compounds of this invention may also be used...in combination with neurotrophic factors such as NGF in order to maximize cholinergic enhancement for the treatment, for example, of ALS, cognitive dysfunction, age related cognitive decline, AD, PD stroke, Huntington's Chorea and TBI; or in combination with agents that slow or arrest AD such as cognition enhancers"

Accordingly, Applicants respectfully request withdrawal of the rejection of claims 25 and 36 under 35 USC § 112, second paragraph, for lack of antecedent basis.

The Examiner also rejected claims 1-6, 8, 10, 15-23 and 25-35 under 35 USC § 112, second paragraph, as allegedly indefinite because the terms "muscarinic agonist" and "amyloid aggregation inhibitor" in claim 1 are indefinite such that one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicants respectfully submit that the declaration of Dane Liston, filed April 6, 2006, provides evidence that one skilled in the art would readily be able to identify specific members of any aforementioned narrow classes (i.e. muscarinic agonists and amyloid aggregation inhibitors). Hence, one skilled in the art, having knowledge of the specific members of these narrow classes, would be reasonably apprised of the scope of the invention.

For the forgoing reasons, applicants respectfully request withdrawal of the rejection of claims 1-6, 8, 10, 15-23 and 25-35 under 35 USC § 112, second paragraph.

In view of the amendments set forth herein and remarks above, applicants respectfully submit that the pending claims are fully allowable, and solicit the issuance of a notice to such effect. If a telephone interview is deemed to be helpful to expedite the prosecution of the subject application, the Examiner is invited to contact applicants' undersigned attorney at the telephone number provided.

The Commissioner is hereby authorized to charge any fees required under 37 C.F.R. §§1.16 and 1.17 or to credit any overpayment to Deposit Account No. 16-1445.

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